

# COMPLIANT



**FOR  
MEDICARE**

**Does It Exist? Is It Scalable?**

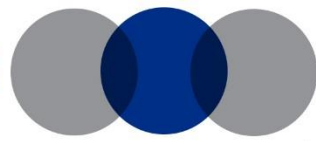


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# Speakers



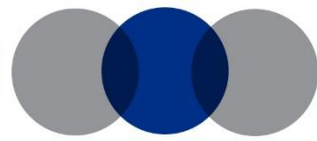
- Zeeshan Hayat
- CEO, Prizm Media



- Karina Hayat
- President, Prizm Media



- Rachel Hirsch
- Senior Associate, Ifrah Law



# Analyzing Lead Generation From An Industry And Legal Perspective



**Query:** How can compliant marketing produce scalable lead generation opportunities for your business while improving your approach to senior selling?



## Housekeeping Checklist for Compliant Lead Generation

Business/Operations	Your Lead Generation Co.
_____ Trained Sales Team	_____ Track Record
_____ Lead Management Software	_____ Lead Management Software
_____ Dialer System (inbound/Outbound)	_____ Compliance Team
_____ Sales Tracking System/Analytics	_____ Best Practices (TCPA, HIPPA, Medicare, OIG)
_____ Processing Team	_____ QA Team
_____ ROI (Rate of Investment)	_____ Access to Ads/Recordings
_____ LVC (Lifetime Value per Customer)	_____ Agreement with defined yearly budget
_____ Marketing Budget (6+ mos)	_____ Reporting/Analytics





# WHAT IS

EXPECT  
RESULTS



vs. Traditional  
Media

RESPONSIBLE MARKETING



# HOW It Works?

**Engage  
Consumer**



**Consumer  
INITIATES  
Response**

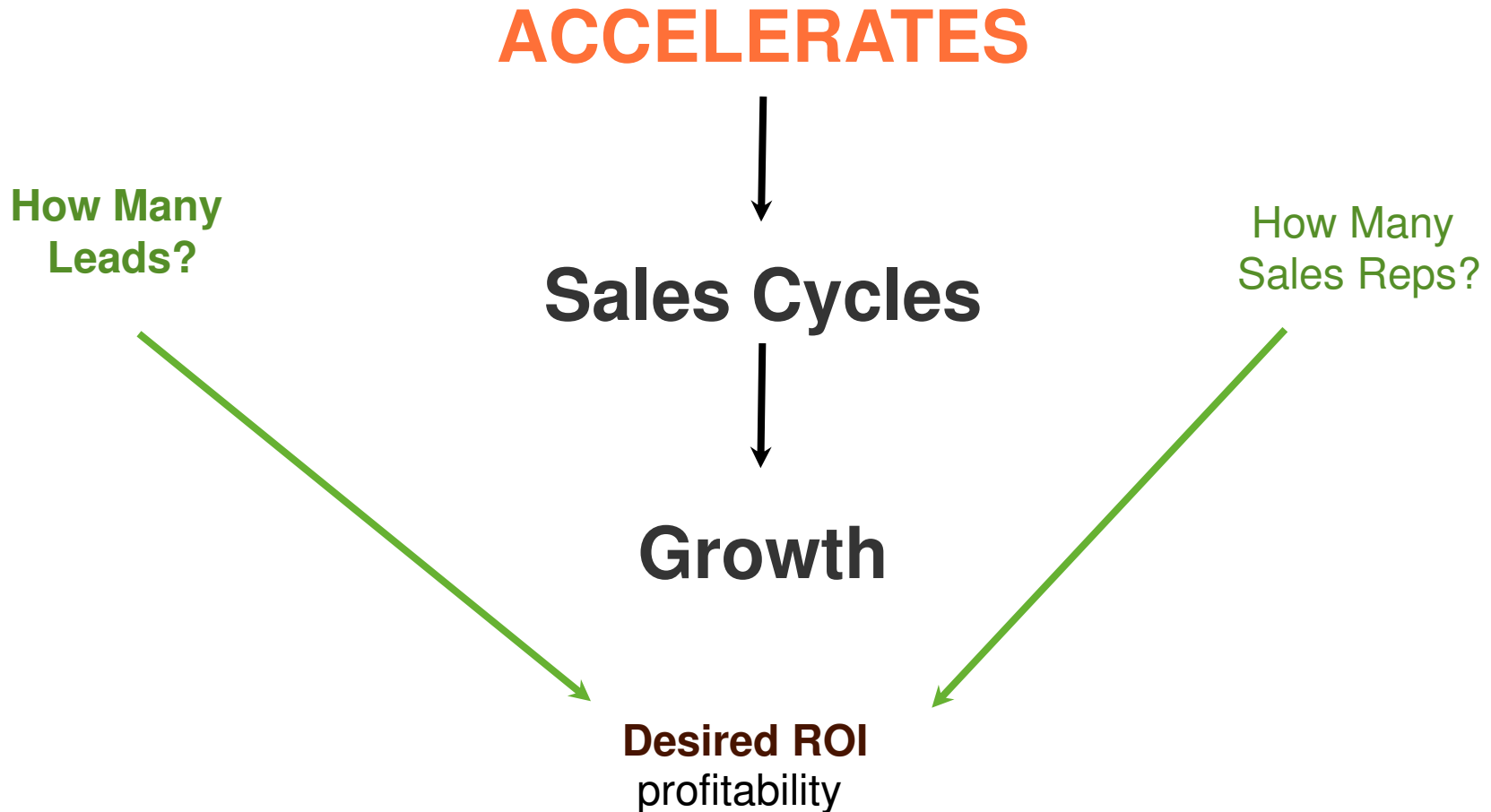


**Consent**

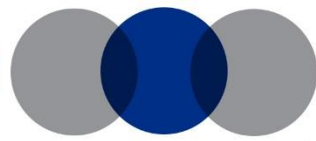




# WHY Is It Important ?







# HOW TO SCALE

**DME:** Logistics &  
Operations Matter



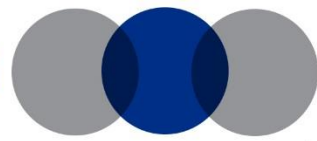


# Lead Generation is a Partnership

50/50



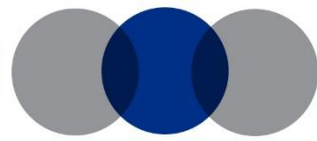
- ✓ Trained & Efficient Sales Team
- ✓ Trained & Efficient Processing Team
- ✓ Telephone System
- ✓ CRM
- ✓ Tracking/Analytics (Measure ROI)
- ✓ Knowing LVC (Lifetime Value per Customer)
- ✓ Min 6 mo Budget



# Your **Lead** Generation Company

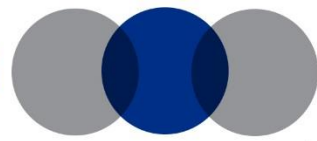


- ✓ Track Record
- ✓ Lead Management System
- ✓ Compliance Team
- ✓ QA Team
- ✓ Reporting/ Analytics
- ✓ Aligned w/ your sales process
- ✓ **BEST PRACTICES**



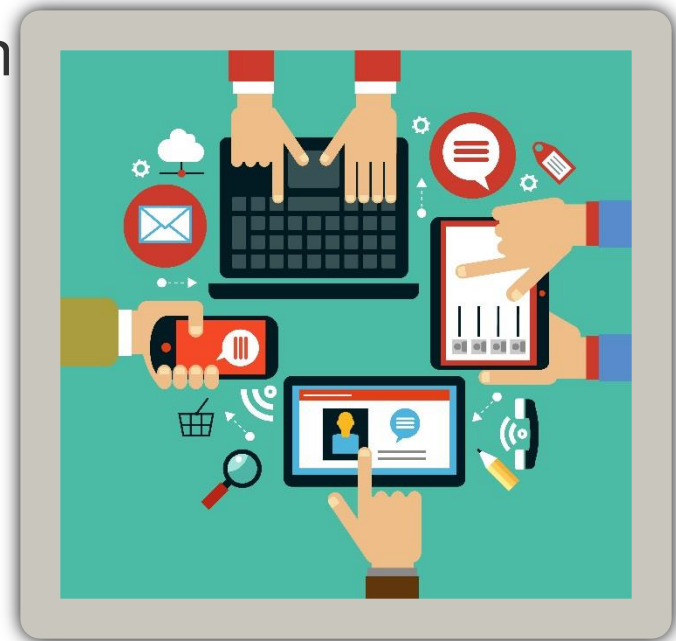
# BEST Practices

- ✓ TCPA Compliance/Non-solicitation
- ✓ Wireless/Landline Scrub (web and phone – not inbound)
- ✓ Record keeping (Consent, recordings, ads...)
- ✓ Confidentiality/Security
- ✓ Marketing Compliance (Disclosure of Product/Service)
- ✓ Master Services Agreement w/ defined yearly budget



# Industry Requirements

- ✓ Telephone Consumer Protection
- ✓ Express consent
- ✓ Disclosure of product service
- ✓ No obligation



**Clear line of Sight**

**Non-Solicitation**





# Industry Requirements: TCPA



## Telephone Consumer Protection Act (47 U.S.C. § 227)

- Restricts telephone solicitations (i.e., telemarketing) and the use of automated telephone equipment, such as automatic dialing systems, artificial or prerecorded voice messages, SMS text messages, and fax machines.



# Industry Requirements: TCPA

## Mobile



**2013 RULE CHANGE:** Marketers Must Receive Prior Express Written Consent From Consumers Before Placing **Autodialed Calls/Texts** Or Generating **Pre-Recorded Messages** To Cell Phones For Telemarketing Purposes.

**EXCEPTIONS:**

- Live (Non-Autodialer) Telemarketing Calls To Wireless Numbers Do Not Require Consent
- Live (Non-Autodialer) Informational Calls To Wireless Numbers Do Not Require Consent

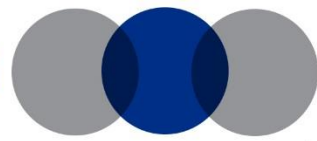
## Landline



**2013 RULE CHANGE:** Marketers Must Obtain Prior Express Written Consent Before Generating **Pre-Recorded Telemarketing Messages** to Consumers' Landlines.

**EXCEPTIONS:**

- Live Telemarketing (With Or Without Autodialer) Calls To Residential Lines Generally Do Not Require Consent
- Live Informational Calls (With Or Without Autodialer) To Residential Lines Do Not Require Consent



# Industry Requirements: TCPA

## What Is Consent?

- Must Be Unambiguous – i.e. “Clear and Conspicuous Disclosure”
- May Not Be A Condition of Purchase
- Requires Consumer to Designate a Phone Number

got consent?

## How Is It Obtained?

May Be Obtained Via:

- Website Form;
- Email;
- Text Message ;
- Telephone Key-Press; or Voice Recording

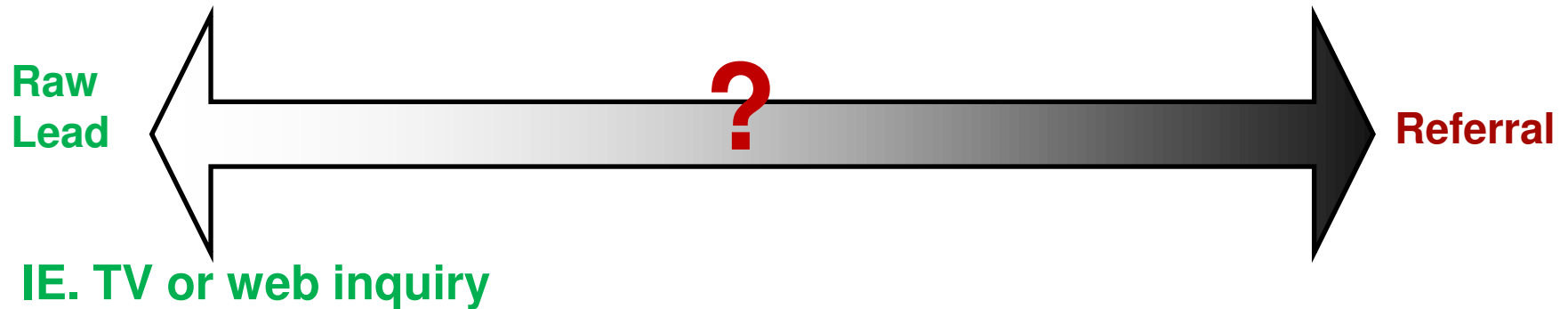
### REMEMBER!

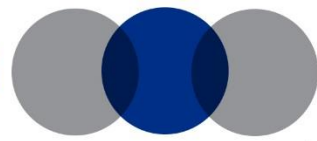
- Companies Should Scrub DNC List
- Consumer Can Revoke Consent

**Who Bears The Burden Of Proof?** Seller/Supplier Bears Burden of Compliance



# Where Things Get Complicated?





# Legal Requirements – Healthcare-Related Statutes



- Medicare Anti-kickback Statute (42 U.S.C. §1320a-7b)



- Beneficiary Inducement Statute (42 U.S.C. § 1320a-7a (a))



- Anti-Solicitation Statute (42 U.S.C. § 1395m(a)(17))



- False Claims Act (31 U.S.C. § 3729)



- False, Fictitious or Fraudulent Claims (18 U.S.C. § 287)



- Stark II Statute (42 U.S.C. § 1395nn)





# Legal Requirements

## Medicare/Medicaid Anti-Kickback Statute (42 U.S.C. §1320a-7b)

- It is a felony for a person or entity to knowingly or willfully solicit or receive any remuneration in return for referring an individual for the furnishing or arranging for the furnishing of any item for which payment may be made under a federal health care program, or in return for purchasing, leasing or arranging for or recommending the purchasing or leasing of any item for which payment may be made under federal health care programs.
- It is a felony for a person or entity to knowingly or willfully offer or pay any remuneration to induce a person to refer a person for the furnishing or arranging for the furnishing of any item for which payment may be made under a federal health care program, or the purchase or lease or the recommendation of the purchase or lease of any item for which payment may be made under a federal health care program.
- **NOTE:** Violation is Presumed, UNLESS a “Safe Harbor” Exception Applies.



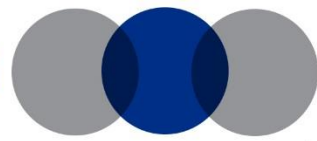
# Is Anti-Kickback Statute Implicated?

- Anti-Kickback Statute Makes It a Crime For **Company A** (DME/HME Supplier) To Give Anything Of Value (e.g., money) To **Company B** (Lead Generation Company) In Exchange For **Company B**:
  - Referring Patients Covered By Government Health Care Program;
  - Arranging For the Referral Of Government Program Patients; or
  - Recommending Purchase Of Product That Is Reimbursed By A Government Health Care Program.

## KEY DISTINCTIONS:

“Purchase a Lead” = **Acceptable**

“Pay for a Referral” = **Violation**



# OIG Special Fraud Alerts And Special Advisory Bulletins



- Discuss Business Arrangements That OIG Believes May Be Abusive.



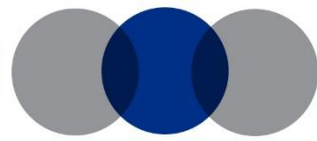
- Educate Health Care Providers Concerning Fraudulent Or Abusive Practices.



- Reflect OIG's Opinions Regarding Application Of Fraud And Abuse Laws.



- Provide Clarity Regarding Certain Business Arrangements.

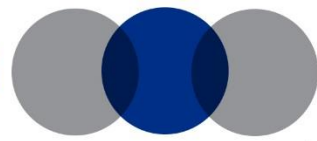


# OIG Advisory Opinion 08-19

## Case Study

- Distinguished Between “Raw/Unqualified Leads” v. “Qualified Leads”
- Determined Not To Seek Enforcement Action Against Parties For The Particular Arrangement At Issue.
- Considered The Following Factors In Reaching Its Determination:
  - No Collection Of “Health Information” By Advertiser.
  - Arrangement Passively Routed Calls/Emails Initiated By Lead.
  - No Active Steering of Patients To Particular Provider.





# Raw/Unqualified V. Qualified Leads



- **“Raw/UnQualified Lead”** – LGC Only Collects Name, Address, And Phone Number of Medicare Beneficiary.
- **“Qualified Lead”** – LGC Collects Additional Information About Beneficiary – e.g., physician’s name, Medicare number, illness/diagnosis, products beneficiary is currently using....





# “Unqualified” v. “Qualified” Leads – Non-Offending Arrangements

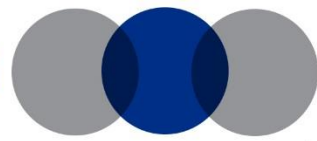
- **“Raw/Unqualified Leads”** – OIG Opinion Reflects Level Of Comfort with DME/HME Providing Compensation On Per Lead Basis.
- **“Qualified Leads”** – Arrangement Must Meet Requirements Of The **Personal Services and Management Contracts Safe Harbor** To Anti-Kickback Statute:
  - Fixed One Year in Advanced (e.g., \$100,000 over next 12 months).
  - Compensation Must Be Fair Market Value Equivalent of LGC’s services.
  - Compensation Cannot Take Into Account Volume of Referrals Generated by LGC.



# You've Purchased A Lead, Now What?

## Telephone Solicitation Statute/Supplier Standard 11

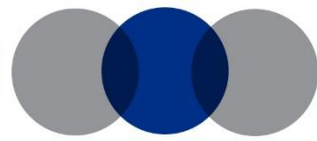
- Arrangement must be examined within context of **42 U.S.C. §1395m(a)(17)** – “**Medicare anti-solicitation statute**” – Prohibits DME company from contacting a Medicare beneficiary by telephone concerning furnishing of covered item of DME unless:
  - ✓ Beneficiary has given “written permission” for contact;
  - ✓ DME company is contacting beneficiary only about an item company has already provided to beneficiary; or
  - ✓ DME company has provided at least one covered item to beneficiary during 15 months preceding the contact.



# What Constitutes “Written Permission” Under Anti-Solicitation Statute

- Checking a check box showing clear consent to be called (not just contacted) by supplier
- Electronic Signature suffices
- [Note Similarities Between Anti-Solicitation Statute and TCPA]
- **BUT:** Anti-Solicitation Statute Unlikely Violated If Prospective Customer Calls Toll-Free Number and Verbally Requests that Supplier Return the Call.

**As in the process of Raw TELEVISION Generated Leads**

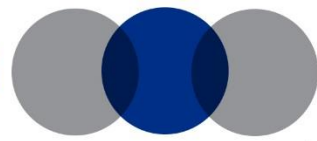


# 2010 OIG Updated Special Fraud Alert:

## “Telemarketing by Durable Medical Equipment Suppliers”

- “A physician’s preliminary written or verbal order is not a substitute for the requisite written consent of a Medicare beneficiary.”
- Response to OIG Alert – CMS Issued “Telemarketing Frequently Asked Questions”
- Clarified that: “If a physician contacts a supplier on behalf of a beneficiary with the beneficiary’s knowledge, and then a supplier contacts the beneficiary to confirm or gather information needed to provide that particular covered item (including delivery and billing information), then that contact would not be considered ‘unsolicited.’”





# And Don't Forget About HIPAA

**Supplier Is Also Subject To Requirements Of **HIPAA**, Which Prohibits The Use Or Disclosure **Protected Health Information (“PHI”)** Not Specifically Permitted Or Required By HIPAA.**

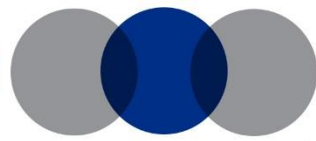
- PHI: Includes information that is created or Received by a health care provider that:

- Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and:

- (i) That identifies the individual; or
  - (ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual **(45 C.F.R. § 164.103).**

- Definition encompasses identification and contact information for a lead, as well as information that relates to the lead's interest in DME/HME.





# Recent Enforcement/Prosecutorial Efforts





# Recommendations For DMEs Purchasing Leads:



Conduct Due Diligence Of Your LGCs. Use Housekeeping checklist



Obtain Requisite BAA Before Disclosing PHI.



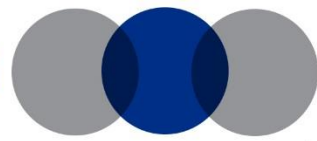
Audit LGCs Call Logs and Advertisements.



Develop Comprehensive Compliance Plan.



Include Indemnification Rights in Your Contracts.



# Questions?



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# Thank you!